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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,269	01/27/2004	Debra Ann Merrill	702-040032	7572

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EXAMINER	
LILLING, HERBERT J	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/765,269	MERRILL ET AL.	
	Examiner	Art Unit	
	HERBERT J. LILLING	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-36* is/are pending in the application.

4a) Of the above claim(s) *17-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *17-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Receipt is acknowledged of the election response filed August 04, 2006.

2. Claims 17-36 are pending in this application.
Claims 1-16 were previously cancelled.

3. Applicant has elected active claims 33-36 for examination.
Applicant has withdrawn from consideration claims 17-32.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33-36 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure, which is not enabling. The structure(s) or components for the claimed "glutamine-rich gluten-free peptide preparation is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The disclosure in the specification lacks the structure(s) as well as any physical data for the claimed peptide(s) which includes the component(s), compound(s), molecular weight, IR, NMR, or any other data as to the peptide(s).

Claims 33-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention lacking the structure and other data for the claimed product per se.

Claims 33-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant has failed to provide the necessary specific information pertaining to the peptide(s) to make and practice the instantly claimed inventions e.g., the specification does not isolate or give the structure of the "protein fragments that cause hypersensitivity...". What is the structure, sequence or any other supporting evidence that clearly indicates the fragment structure or sequences?

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 33-36 are rejected under 35 U.S.C. 102(e) as anticipated by

Blom et al U.S. 5,741,705 or Auriol et al U.S. 5,554,508

Each of the references teaches a hydrolysate of wheat by enzymatically hydrolyzing the wheat with a protease at a neutral or alkaline pH.

Blom teaches compositions, which recites the following:

> From the results it can be seen that the gluten hydrolysate from this invention does not given an acute cytotoxicity and that the cells can be cultured using the gluten hydrolysate from this invention.

An example teaches a product which is considered within the scope of the claimed inventions.

> A 8% dispersion of vital gluten is hydrolysed with 0.1% (E/S) of the commercially available enzyme preparation pepsin orthana 1:10,000 NF (P.C.A. Diagnostica, Haarlem, The Netherlands) at 50.degree. C. for 16 hours. The pH is initially set at pH 1.5 with hydrochloric acid and not controlled during further hydrolysis. After hydrolysis the enzyme is inactivated via a heat treatment of 95.degree. C. for 1 minute. Residual intact protein and insoluble components are removed via centrifugation for 5 minutes at 2500 g and the obtained effluent is subsequently ultrafiltered. Preferably membranes with a molecular weight cutoff of 10,000 Dalton are used. The obtained ultrafiltration permeate is concentrated via evaporation and is then spray dried.
>
> Detailed Description Text (31):
> To the basic RPMI-1640 medium obtained from the Gibco's select Amine kit the supplement without the L-glutamine was added. Instead of L-glutamine as present in the supplement 3.1 g/l of the obtained gluten hydrolysate was added. Additionally the free amino acids cysteine, arginine and hydroxyproline are supplemented to compensate for the low levels of these amino acids in the obtained gluten hydrolysate. The results are summarized in Table 5.

Auriol et al is considered to produce a product from the hydrolysis of wheat gluten with an enzyme (Alcalase) at an alkaline pH within the scope of the claimed inventions

> Example 2: Alcoholysis of Wheat Gluten Peptides
> The wheat gluten peptides were prepared by hydrolyzing gluten with subtilisin (Alcalase) at pH=8: the average molar mass of the water-soluble peptides determined according to the conditions described in Example 1 is 4200.

The product(s) obtained by the above reference is/are considered to be within the scope of the inventions in view of the following decisions:

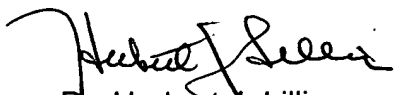
> It is well settled that if a reference reasonably teaches a product which is identical or substantially identical or are produce by identical or substantially identical process, the PTO can require an applicant to prove that the prior art products do not inherently possess the characteristics of his claimed product. A rationale given for shifting the burden of going forward to applicant is that the PTO does not possess the facilities to manufacture or to obtain and compare prior art products, see **In re Brown**, 459 F.2d 531, 535,173 USPQ 685, 688 (CCPA 1972); **In re Best**, 562 F.2d 1252, 1255,195 USPQ 430, 433-434 (CCPA 1977).

6. **No claim is allowed.**

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Examiner Lilling whose telephone number is 571-272-0918** and **Fax Number** is (703) 872-9306 or SPE Michael Wityshyn whose telephone number is 571-272-0926. Examiner can be reached Monday-Thursday from about 5:30 A.M. to about 3:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://portal.uspto.gov/external/portal/pair**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H.J.Lilling: HJL
(571) 272-0918
Art Unit **1651**
August 21, 2006



Dr. Herbert J. Lilling
Primary Examiner
Group 1600 Art Unit 1651